DEVELOPMENT OF A HIGH DENSITY PERCUTANEOUS CONNECTOR SYSTEM

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Abstract

This report summarizes activity over the period from April through July 1997 on NIH Contract N01-DC-7-2103, "Development of a High Density Percutaneous Connector System". This quarter is the first one covered by the renewed contract. During this period an organizational meeting was held at HMRI to review the results of the final series of animal tests completed during the last contract period and to discuss future improvements in the connector. In addition the goals of the animal testing program for this contract and the approximate number of animals in each series were discussed. Finally, a new connector with larger pins was produced and the mate/demate performance of this system checked.

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I. Background and review of contract requirements

This report summarizes activity from April through July 1997, on NIH Contract N01-DC-7-2103, "Development of a High Density Percutaneous Connector System". Over the course of this contract, a high density, planar, low profile connector system is being developed that incorporates pad grid array technology. This technology has unique advantages as applied to a percutaneous interconnect system. In particular the connector system will be low in profile, easy to clean, sealed against ingress of contaminants, offer low mechanical resistance to mating and demating and provide a very high number of contacts in a small diameter. The connector system will be implanted in a suitable animal model and the appropriate electrical, mechanical, and biocompatible properties of the system will be assessed. The specific technical requirements of this connector system as detailed in the contract are explained below:

- The connector will incorporate a pedestal that can be attached to the skull in a mechanically stable manner. The pedestal will be designed to accept a replaceable connector assembly. All materials of the pedestal in contact with tissue will be biocompatible and the profile of the pedestal will be low enough to minimize any physical trauma during mating and demating of the connector or due to normal physical activities.

- The connector assembly will be high-density with at least 70 contacts. The electrical isolation between the contacts or between the contacts and the body should withstand at least 18 volts without breakdown. The connector contacts when mated should be capable of passing up to 20 mA of current with less than a 1.0 volt drop across the connection. A simple method of mating and demating the upper and lower surfaces of the connector should be provided. In addition, a convenient means to attach electrical leads to the connector is needed.

- The connector will be designed from materials that are durable and can withstand the physical abuse from normal activities of daily living. The interface between the connector and the skin must be such that the passage of microorganisms into the body and fluid drainage out of the body is prevented.

- The connector assembly will have at least 5 separate loops of insulated wire, each at least 2 inches in length, implanted in the subcutaneous space of the scalp. An 18 volt bias will be maintained on the connector contacts and insulated wires relative to an implanted platinum wire connected to one of the unused contacts. The leakage current of the wires will be monitored and if more than 10 nanoamperes of current is detected, the source of the leakage will be identified and corrected.

- The performance of the connector system will be tested in a suitable animal model. After six months of implantation, the connector assembly will be explanted and the following gross and microscopic examinations performed: the attachment of the pedestal to the skull; the attachment of the skin and soft tissue surrounding the pedestal to the pedestal wall; the reaction of adjacent tissue to the implanted device.

- Finally, design changes and improvements, if needed, will be recommended. A set of connectors will be fabricated and sent to the NIH for implantation into primates and eventually humans as part of their ongoing research.

II. Introduction

This quarter marked the beginning of work under the renewed contract. During this period an organizational meeting was held at HMRI to review the animal tests completed during the last contract, and to discuss future improvements in the connector. In addition the goals of the animal program for this contract, and the approximate number of animals in each series were discussed. Finally, a new connector with larger pins was produced and the mate/demate performance of the system checked.

III. Organizational Meeting

An organizational meeting was held on June 25th at HMRI in Pasadena, California. In attendance were Bill Agnew, Leo Bullara, Randy Carter, Doug McCreery, and Al Lossinski from HMRI, Tim Piwonka-Corle and Ky Huynh, from PI Medical, and Dave Edell, consultant to the project. A separate meeting was later held with Dr. Derald Brackmann, consulting surgeon. The purpose of the meeting was to:

- Review the contract requirements.
- Review the results of the implantation studies carried out during the first three years of the original contract.
- Review the current connector design and suggested improvements to this design.
- Discuss the goal of the animal experimentation in this contract and to plan for the different series of animal testing.
- To make an action plan and agree on commitments for the first year of the contract.

The highlights of the meeting with particular emphasis on the conclusions drawn from the discussions are listed below.

Review of Contract Requirements

The requirements of the new contract were briefly discussed. The main items to be addressed during the continuation project are to improve the skin integration of the connector assembly, improve the reliability of the connections and provide a simple method of mating the top and percutaneous portions of the system. Since the end goal of this contract is to provide connectors for use in humans, the materials used to build the connector will need to be qualified for such use.

Review of Implantation Studies

There was evidence of new bone growth all the way around the pedestal, in many cases well into the second layer of titanium beads. There was an issue, however, with the soft tissue integration. The integration varied by animal with larger animals performing better than smaller ones. The soft tissue integration problem seemed to be driven by the subcutaneous test loops. These loops formed pockets underneath the skin which promoted inflammation and infection. The areas of infection showed evidence of chronic inflammation including Giant macrophages and Lymphocytic cells. There was no correlation observed between the amount of osseointegration and the amount of inflammation at the skin surface on the test animals. After reviewing the implantation evidence, the group concluded that it will be possible to get a good interface between the titanium and the skin if the large test loops surrounded by silicone tubing were replaced with a flat ribbon cable anchored to the surface of the bone.

Review of Connector Design and Suggested Improvements

The new pedestal will incorporate a ramp that brings the wires out at the level of the skull, Figure 1. In addition all the wires will be bundled together so that they exit the connector at one point rather than having five separate test loops as in the previous design. This design change should help to alleviate the problems associated with tissue damage and subsequent infection around the wires.

An additional problem that was seen on the old connectors is intermittent contact on some of the pins. This issue was discussed in Quarterly Progress Report #11 of contract N01-DC-4-2103.

To eliminate this problem the pin diameter was increased from 0.0125" to 0.017". This increase gives the pins sufficient area to make reliable contact with the current elastomer according to the elastomer manufacturer, Shin-Etsu. Two connectors have been built using the larger pins and their mate/demate performance tested. The results of these tests are discussed in section IV below.

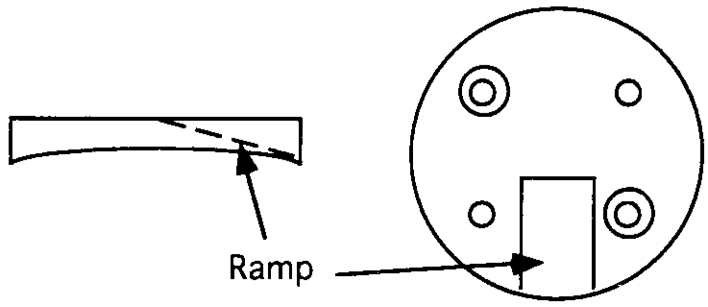

Figure 1. Schematic of proposed base pedestal.

To improve the long term reliability of the connector we will investigate using a fritted ceramic material to replace the epoxy ceramic matrix that holds the pins in place. The fritted material should provide the same insulation qualities as the epoxy ceramic while presenting a much harder surface to the outside world. The pin size will be increased to 0.018" in the ceramic pad grid array giving further robustness to the system. If a fritted pad grid array is used, we will need to reexamine the bonding of the epoxy and the silicone in the backpot area.

A further simplification in the manufacturing and assembly process can be obtained by incorporating a flex circuit ribbon cable into the lower connector. An anisotropic conductive paste could be used to join the back surface of the pad grid array to the circuit array. The advantages of this technology is that it will allow a standard connector to be produced to which different researchers can simply connect a variety of electrode patterns. Thus connectors would not have to be custom ordered with the ensuing delays in procuring the materials and assembly. In addition the cost of the system will be reduced because much of the hand assembly work will be eliminated and the connectors can be built and tested in larger batches; then stocked for immediate delivery. The disadvantage of this design is that it introduces one more electrical connection into the system that can lead to failure after implantation.

Dave Edell suggested using a silicon wafer as the flex circuit element. Silicon is biocompatible and can be easily overcoated with metallic leads from bonding pads using standard processes. In addition, silicone will bond well to it so that the resulting connections can be sealed against ions that may form leakage paths after implantation.

It was decided at the meeting to pursue parallel tracks of standard silicone or Parylene coated wires and a ribbon cable design. The ribbon cable design would be moved to animal testing only after it had proved itself out in the in-vitro tests.

One of the objects of this contract is to design an improved system for mating the external and percutaneous portions of this connector. Two broad approaches for solving this problem were discussed at the meeting. Either changing the design of the connector, or using a tool to do the installation. The approach that will be first attempted is to change the design of the connector so that it can be easily attached by the user. One method is to put a lip on the shell surrounding the percutaneous section with large sloped threads so that the two halves can be attached using a 1/4 turn of the upper connector. The lip should be approximately 1mm tall so that it has sufficient strength to compress the elastomer. This extra material should not significantly impact the height of the connector above the skin line. Leo Bullara pointed out that for the best performance we will need multiple parallel threads. In addition, the lip should be removable so that if it becomes accidentally damaged due to cross threading etc., the entire connector will not have to be replaced.

Animal Testing

In the contract proposal, six series of animal tests were proposed to understand the different performance aspects of the test. The animal tests are only being performed where strictly necessary and only after extensive in-vitro testing of the components. The goals of each series are described below.

SERIES 1. Dummy connectors designed to test the various strategies for skin integration without the influence of the lead wires. Three different surfaces will be tested on a total of nine cats. Three of the grooved titanium surfaces were used in the last contract. The groove depth and height were selected based on both the published work of Chehroudi Gould and Brunette at the University of British Columbia and our own experience with the last contract. In addition three brushed titanium surfaces and three of the Tantalum sponge surfaces will be examined. Dave Edell has had success with long term skin integration on the brushed titanium surfaces and the manufacture of the porous Tantalum sponge has reported good results in bone and skin integration studies with their material. During these tests care will be taken to keep the post operative procedure the same for all animals. Implantation time: Pedestal 4 weeks, Second stage 12 weeks - Total 16 weeks.

SERIES 2. Designed to test in vivo performance of the new pedestal and cable assembly. This test will be changed slightly for the one described in the proposal. The comparison test with the original connector design will be eliminated. Only the new style of connector will be implanted. We will not implant the old connector as a benchmark because it was shown in the previous contract that the bulky test loops consistently cause the connector to fail. PI Medical will undertake a long term saline soak of the connectors before beginning these experiments to ensure that the new materials will last in an environment that simulates an implant. Four cats will be used in this experiment. Implantation time: Pedestal 4 weeks, Percutaneous section 12 weeks - Total 16 weeks.

SERIES 3. Designed to test the mate/demate system and the electrical bias testing under in-vivo conditions. This series represents the first test of the full connector system. Four cats will be used. Implantation time: Pedestal 4 weeks, Percutaneous section 8 weeks. If satisfactory performance is obtained from these connectors, the test will not be terminated at 8 weeks, but rather roll into the long term (6 month) testing required by the contract. This step would be taken to minimize the number of animals used in the overall study.

SERIES 4. Test of DC stimulation to promote healing. If poor skin integration is obtained in series 1-3 then a series of experiments will be designed to test the affect of current stimulation on healing. Six cats will be used in this series. Implantation time: Pedestals 4 weeks, Percutaneous section with stimulation 8 weeks.

SERIES 5. Long term implantation tests. These are the 6 month implantation tests as required by the contract. Eight animals will be tested as required by the contract.

SERIES 6. Primate testing at the University of Washington. This testing will be done in conjunction with Dr. Sandy Spelman who is leading a team working on cochlear electrode arrays. This testing will be done as primates and cochlear electrode arrays become available. The time frame and duration of the tests will be driven by the needs of the cochlear group. They are initially planning six month implantation tests.

One significant issue that may cause us to modify our plans for animal testing, or delay the completion of the contract is the availability of test animals. According to Bill Agnew, HMRI currently has only one source of cats in the US. This issue will be actively followed, but is largely out of our control.

IV. Testing the Mate/Demate Performance of the Connector

In both in-vitro and in-vivo testing carried out under the previous contracts it was occasionally, observed that an elastomer failed to make contact between certain pins on the connector. Rotating or replacing the elastomer corrected the problem. This intermittent failure was likely caused by the fact that the surface area of the pins is 53% smaller than suggested by the elastomer manufacturer (the pin diameter is 0.0125" rather than the 0.017" as suggested by the manufacturer). With the smaller pins, in some instances, the random arrangement of the fibers in the elastomer does not make contact with all the pins.

There are two solutions to this problem, either the anisotropic elastomers can be tested and sorted to identify which elastomers work with which connectors, or the surface area of the pins can be increased. Two new connectors were built with 0.017" pin diameters. One of these was shipped to Martin Bak for testing at the NIH. The mate/demate performance of the second one was tested at PI Medical.

To perform the test a conductive paste was used to common all the pins of the lower connector together. The paste was then used to make contact to the titanium shell. This step simplified the testing because one test lead of the multimeter could be used to probe the pins on the upper connector while the other one only needed to contact the titanium shell. Thus the step of either bonding wires to the lower connector or locating and probing adjacent pins on both the top and bottom of the connector was avoided.

In the first measurement the two halves of the connector were joined using the supplied #0-80 screws and the RMA type anisotropic elastomer material from Shin-Etsu. The previously developed torque procedure which evenly tightens the two screws to 14 in-oz was also used to assure that the elastomer was uniformly compressed. A Fluke 79 multimeter was used to measure the resistance of each pin in the 64 x 64 array of the connector. The results are reported in Table 1 below. All measurements in this table are in Ohms. These results are near the limit of detectability for this instrument. Shorting the leads of the multimeter directly together gave a reading of 0.4 Ohms.

Row/ Column #	1	2	3	4	5	6	7	8
1	0.5	0.5	0.5	0.4	0.4	0.4	0.5	0.4
2	0.5	0.5	0.4	0.5	0.5	0.5	0.5	0.5
3	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
4	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.6
5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
6	0.5	0.5	0.5	0.4	0.5	0.5	0.5	0.5
7	0.5	0.5	0.5	0.4	0.5	0.5	0.5	0.5
8	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5

The connection procedure was repeated 36 times with this elastomer. The resistance was not measured each time, only the continuity was checked. On the 24th connection, one of pins showed an open circuit. The mate/demate procedure was repeated two more times and the same pin measured open in all three cases. Due to the symmetry of the structure, any given elastomer can be put into the connector in one of four possible orientations represented by all the permutations of a 180 degree rotation and a flipping of the elastomer. Each of the possible orientations was tried twice to determine if the problem was with the elastomer, or the connector pins themselves. In many cases a different orientation of the elastomer resulted in continuity being measured on all the pins. When an open pin was measured, it was found that the failure followed the orientation of the elastomer and was not tied to one specific pin of the array.

Both the elastomer and the two halves of the connector were visually examined under an optical microscope. No visible damage was seen in either the elastomer or on the connector pin which lost continuity. This observation is consistent with the known failure mode of the elastomer. According to Shin-Etsu, the dominant failure mode is for the small wires running through the elastomer to break inside the silicone. This breakage can lead to either an open circuit or intermittent contact.

The elastomer was replaced with a new piece of material and the mating tests continued. On the 39th mating, the thinned wall on the head of one of the #0-80 screw cracked so that it could not be tightened to the proper torque specification. Many open contacts were subsequently measured on the connector. Both screws were replaced and the mate/demate testing continued. Continuity was again measured on all the pins until the 50th mating. At this point one of the screw heads again broke. The testing was then stopped.

In summary, the following conclusions were drawn from this experiment:
• The new connector is good for multiple mate/demate cycles. Continuity on all the pins was measured for up to 50 cycles.
• It is important to torque the screws evenly and thus to uniformly compress the elastomer. Failures were observed due to non-uniform compression of the elastomer.
• There are occasional failures that can be attributed to the anisotropic elastomer. Replacing the elastomer corrects these failures. The elastomer should be replaced approximately every 25 mating cycles.
• The thinned sidewalls of the screws crack after 15-25 mating cycles so that the required torque cannot be achieved. The current screws with the smaller heads should be replaced approximately every 10 mating cycles.

VIII Activities During the Next Contract Period

- Obtain and implant pedestal and dummy connectors for Series 1 animal testing.
- Design new base pedestals incorporating the ramped feature.
- Begin development work on Parylene coated wires.
- Develop design ideas for connecting the external and percutaneous sections of the connector.

IX References

Chehroudi, B. Gould T.R.L., and Brunette D.M. (1988) "Effects of a grooved epoxy substratum on epithelial cell behavior in vitro and in vivo." J. Biomed. Mater. Res. 22, 459-473.

Chehroudi, B. Gould T.R.L., and Brunette D.M. (1989) "Effects of a grooved titanium-coated implant surface on epithelial cell behavior in vitro and in vivo," J. Biomed, Mater. Res. 23, 1067 1085.

Chehroudi, B. Gould T.R.L., and Brunette D.M. (1991) "A light and electron microscopic study of the effects of surface topography on the behavior of cells attached to titanium-coated percutaneous implants," J. Biomed. Mater Res. 25, 387-405.

Chehroudi, B. Gould T.R.L., and Brunette D.M. (1992) "A role of connective tissue in inhibiting epithelial downgrowth on titanium-coated percutaneous implants," J. Biomed. Mater Res. 26, 493-515.

Piwonka-Corle, T.R. Principal Investigator (1996-1997) "Development of a Percutaneous Connector System," Quarterly Progress Reports. Contract No: N01-DC-4-2103.